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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,273	04/10/2001	Roland Cherif-Cheikh	05339-014003	2832

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225 FRANKLIN ST  
BOSTON, MA 02110

EXAMINER
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LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/02/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/832,273

Applicant(s)

CHERIF-CHEIKH, ROLAND

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-8 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Double Patenting*

Claims 6-8 and 22-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,695,463 in view of Hutson, 5,242,416. Cherif-Cheikh '463 discloses the invention substantially as claimed, except for a removable cap which covers the sleeve. Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed. Since both Cherif-Cheikh and Hutson teach a syringe with a protective sheath, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap as taught by Hutson on the Cherif-Cheikh sleeve in order to protect the needle before, during or after use, as taught by Hutson.

Claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,695,463 in view of Hutson, 5,242,416, and further in view of Whitley, 5,399,170.

Cherif-Cheikh '463 discloses the invention substantially as claimed, except for a removable cap which covers the sleeve, and except for a releasable lock to inhibit the movement of the plunger into the housing.

Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed. Since both Cherif-Cheikh and Hutson teach a syringe with a protective sheath, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap as taught by Hutson on the Cherif-Cheikh sleeve in order to protect the needle before, during or after use, as taught by Hutson.

Moreover, Whitley '170 also discloses a syringe with a protective sheath, and further discloses a releasable lock as claimed in order to prevent movement of the plunger prior to use, see column 3, lines 6-17. It would have been obvious to provide a releasable lock as taught by Whitley on the Cherif-Cheikh '463 syringe, as it would be desirable to prevent movement of the plunger prior to use.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al., 5,634,906, in view of Hutson, 5,242,416.

Haber et al. disclose the invention substantially as claimed. In particular, Haber et al. disclose an injection device comprising a hollow housing (26), a hollow needle (36) affixed to the distal end of the housing and extending longitudinally within said housing; a plunger (44, see column 5, lines 39-42) arranged to slide within the proximal end of the housing; a hollow sleeve (6) slidably connected to the distal end of the housing and arranged to cover the needle prior to injection (see Figure 3) and to retract into the housing during injection (see Figure 4); wherein the device is designed such that when the sleeve is pressed against the subject, and when the plunger is pushed into the housing, the composition is pushed from the housing through the needle and into the subject (see column 6, lines 6-11.)

As to claim 7, the proximal end of the housing (26) comprises a flange (see proximal end of 26.)

As to claim 8, the proximal end of the plunger (44) comprises a flange (see 44 in Figure 1).

As to claims 23 and 24, the housing (26) contains the liquid or semi-solid composition.

However, Haber et al. do not disclose a removable cap which covers the sleeve.

Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed. Since both Cherif-Cheikh and Hutson teach a syringe with a protective sheath, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap as taught by Hutson on the Cherif-Cheikh sleeve in order to protect the needle before, during or after use, as taught by Hutson.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al., 5,634,906, in view of Hutson, 5,242,416.

Haber et al. disclose the invention substantially as claimed, except for a removable cap which covers the sleeve, and except for a releasable lock to inhibit the movement of the plunger into the housing.

In particular, Haber et al. disclose an injection device comprising a hollow housing (26), a hollow needle (36) affixed to the distal end of the housing and extending longitudinally within said housing; a plunger (44, see column 5, lines 39-42) arranged to

slide within the proximal end of the housing; a hollow sleeve (6) slidably connected to the distal end of the housing and arranged to cover the needle prior to injection (see Figure 3) and to retract into the housing during injection (see Figure 4); wherein the device is designed such that when the sleeve is pressed against the subject, and when the plunger is pushed into the housing, the composition is pushed from the housing through the needle and into the subject (see column 6, lines 6-11.)

However, Haber et al. do not disclose a removable cap which covers the sleeve.

Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed. Since both Cherif-Cheikh and Hutson teach a syringe with a protective sheath, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap as taught by Hutson on the Cherif-Cheikh sleeve in order to protect the needle before, during or after

Moreover, Whitley '170 discloses a syringe with a protective sheath and further discloses a releasable lock as claimed in order to prevent movement of the plunger prior to use, see column 3, lines 6-17. It would have been obvious to provide a releasable lock as taught by Whitley on the Cherif-Cheikh '463 syringe, as it would be desirable to prevent movement of the plunger prior to use.

***Response to Arguments***

Claim 6 was previously indicated as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, upon further consideration, Examiner believes that the above rejection is proper.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L. 

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

11/28/03